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(54) ANTIARTHRITIC OR ANTIRHEUMATIC PREPARATION, FOOD OR FEED

(57)Abstract:

PROBLEM TO BE SOLVED: To solve such a problem that the relaxation of rheumatics and arthri tis due to the intake of calcium are difficult, a problem that the combination of glucosamine salt with a cartilage extract relaxes the arthritis, but is not largely effective for the rheumatics accompanying the ache of the nervous system, and a problem that a sufficient effect can not be obtained only by the anti-rheumatic action of Withaia Somnifera Dunal plant extract.

SOLUTION: This antiarthritic or antirheumatic preparation is characterized by containing the Withaia Somnifera Dunal plant extract and the cartilage extract.

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CLAIMS

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[Claim(s)]

[Claim 1] The anti-arthritis agent or anti-rheumatism agent [claim 2] characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract The anti-arthritis agent according to claim 1 or anti-rheumatism agent [claim 3] whose Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is an extract The anti-arthritis agent according to claim 1 or 2 or anti-rheumatism agent [claim 4] by which the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is obtained originally, and is condensed 5 times to 15 times of a natural vegetable root An anti-arthritis agent or an anti-rheumatism agent [claim 5] given in any 1 term of claims 1-3 which contain WITAFERIN (Withaferin), site INDO sides (sitoindoside), or WITANORAIDO (Withanolide) in the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract An anti-arthritis agent or an anti-rheumatism agent [claim 6] given in any 1 term of claims 1-4 to which a cartilage extract is obtained from the mammals, fishes, or birds, and contains a chondroitin salt in a cartilage extract An anti-arthritis agent or an anti-rheumatism agent [claim 7] given in any 1 term of claims 1-5 whose gestalten of pharmaceutical preparation are liquids and solutions, powder, a granule, a capsule, or a tablet Food characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract [claim 8] Food according to claim 7 whose Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is an extract [claim 9] Food according to claim 7 or 8 with which the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is originally obtained, and is condensed by 10 or more times of a natural vegetable root [claim 10] Food given in any 1 term of claims 7-9 which contain WITAFERIN (Withaferin), site INDO sides (sitoindoside), or WITANORAIDO (Withanolide) in the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract [claim 11] Food given in any 1 term of claims 7-10 to which a cartilage extract is obtained from the mammals, fishes, or birds, and contains a chondroitin salt in a cartilage extract [claim 12] Feed characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract

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DETAILED DESCRIPTION

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[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to the pharmaceutical preparation which improves arthritis or rheumatism, food, for example, health food, or feed.

[0002]

[Description of the Prior Art] It was thought that arthritis and rheumatism had a certain cause and were conventionally generated to the bone, and intake of the calcium food for making a bone strong or calcium consolidation auxiliary food was confirmed. Moreover, in order to raise bone density, the health food which strengthened calcium to soybean isoflavone is developed. Furthermore, what combined the glucosamine salt which is the configuration monosaccharide of chitosan as palliative of arthritis, and the cartilage extract is known. The nourishment sthenia of the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, strong energy, anti-stress, and an anti-rheumatism operation have recently been checked. The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetation is vegetation of Solanaceae which grow wild in India, Nepal, or the Middle East, it is called a winter cherry (Winter Cherry) by the English name, and is called ASHUWAGANDA (Ashwagandha) in India, and also has the another name of the India ginseng radix. In India, from ancient times, more, the root and the leaf were made into medical use, put vegetable desiccation powder into tea, milk, yogurt, etc., and have been used as nourishment strong food. The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract end of a high content has come to be obtained with development of an extract technique. Moreover, the cartilage extract of a cow and a shark is used as an arthritis remedy by the chondroitin sulfate being included.

[0003]

[Problem(s) to be Solved by the Invention] However, it is difficult to ease arthritis and rheumatism only by a calcium consolidation or bone density lifting. Moreover, about a glucosamine salt and a cartilage extract, even if arthritis is eased in combination, there is no effectiveness in the rheumatism accompanied by the pain of a nervous system not much. Moreover, there were problems — effectiveness sufficient in just an anti-rheumatism operation of the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract is not acquired.

[0004] Thus, the pharmaceutical preparation, food, and feed which can treat simultaneously the arthritis which comes from the cartilage injury of a joint etc., and the rheumatism accompanied by the pain of a nervous system, and can expect effectiveness were desired.

[0005]

[Means for Solving the Problem] Then, this invention persons found out that it was [ effectiveness ] more larger to have performed anti-arthritis or an anti-rheumatism operation simultaneously, and to take in simultaneously rather than independent intake by taking in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, as a result of examining many things. Consequently, the anti-arthritis which can take in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract or anti-rheumatism pharmaceutical preparation, food, or feed was obtained. This invention is completed based on the above-mentioned knowledge.

[0006] This invention Namely, (I) The anti-arthritis agent or anti-rheumatism agent characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, (II) An anti-arthritis agent or an anti-rheumatism agent given in (I) whose Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is an extract, (III) The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is what is obtained originally. An anti-arthritis agent or an anti-rheumatism agent given in (I)

condensed 5 times to 15 times of a natural vegetable root, or (II), (IV) In the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, WITAFERIN (Withaferin) An anti-arthritis agent given in any 1 term of (I) containing site INDO sides (sitoindoside) or WITANORAIDO (Withanolide) - (III) or an anti-rheumatism agent, (V) An anti-arthritis agent or an anti-rheumatism agent given in any 1 term of (I) to which a cartilage extract is obtained from the mammals, fishes, or birds, and contains a chondroitin salt in a cartilage extract - (IV), (VI) An anti-arthritis agent or an anti-rheumatism agent given in any 1 term of (I) - (V) whose gestalt of pharmaceutical preparation is liquids and solutions, powder, a granule, a capsule, or a tablet, (VII) Food characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, (VIII) the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract — an extract — it is (VII) — the food of a publication — (IX) The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is obtained originally, and it is condensed by 10 or more times of a natural vegetable root (VIII). (VII) a publication Food, (X) In the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract, WITAFERIN (Withaferin) Food given in any 1 term of (VII) - (IX) containing site INDO sides (sitoindoside) or WITANORAIDO (Withanolide), (XI) A cartilage extract is what is obtained from the mammals, fishes, or birds. Food given in any 1 term of (VII) - (X) which contains a chondroitin salt in a cartilage extract, (XII) It is related with the feed characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract.

[0007]

[Embodiment of the Invention] As long as the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetation in this invention contains for example, WITAFERIN (Withaferin), site INDO sides (sitoindoside), and a WITANORAIDO (Withanolide) component, what grew artificially what acted naturally as the ground student is sufficient as it. Moreover, although this vegetation may contain one component or two or more components for the above-mentioned component, its thing containing two or more components is desirable. Furthermore, this vegetation may contain WITARAIDO as a component.

[0008] For example, WITAFERIN A (WithaferinA) is contained in WITAFERIN. For example, the site INDO side VII, the site INDO side VIII, the site INDO side IX, and the site INDO side X are included in site INDO sides. For example, WITANORAIDO D and WITANORAIDO E are contained in WITANORAIDO.

[0009] It is more desirable to use an extract, although what the Withania sum NIFERADEYUNARU plant extract dried the extract which extracted the active principle with the solvent etc. and was obtained, for example from a root, a stem, a leaf, a flower, or fruits of the vegetation etc. or the root of the vegetation, a stem, a leaf, a flower, or fruits, and was used as powder may be used. The extract contains the about 10 times as many active principle as this compared with what was used as desiccation powder.

[0010] Although the extract of the Withania sum NIFERADEYUNARU vegetable extract may use what was extracted from which thing of the root of for example, the Withania sum NIFERADEYUNARU vegetation, a stem, a leaf, a flower, or fruits, there are many contents of WITAFERINA, WITANORAIDO D, WITANORAIDOE, the site INDO side VII, the site INDO side VIII, the site INDO side IX, or the site INDO side X, and it is desirable to use the part of the root which can extract the stable amount.

[0011] Although the Withania sum NIFERADEYUNARU plant extract can usually be used anything if it is obtained originally, as for the extract, it is desirable to use the thing containing the active principle more preferably condensed 10 times to 12 times 7 times to 15 times 5 times to 15 times in the natural vegetable root.

[0012] Few objects can also be used for it although many things of the quantitative formula in the Withania sum NIFERADEYUNARU vegetable extract are desirable. For example, that in which WITAFERIN A is contained just over or below 2.00% as WITANORAIDO just over or below 0.15% can be used for the content.

[0013] The extract of the component from the Withania sum NIFERADEYUNARU vegetation can be performed using organic solvents, such as water, hot water, ethyl alcohol, or an acetone. Moreover, the mixed solvent or water solvent which combined them is sufficient, and even if those mixed rates are arbitrary, they are not cared about, and they are not limited to especially this approach.

[0014] As long as the cartilage extract in this invention is an animal which has cartilages, such as birds, such as fishes, such as the mammals, such as a cow, a goat, a whale, a sheep, or a pig, a shark, a ray, or a tuna, an ostrich, or a hen, it may be obtained from what kind of animal. Moreover, as long as it contains a chondroitin salt in a cartilage extract, what kind of animal is sufficient.

[0015] If the manufacturing method of a cartilage extract is an approach generally learned, after it collects cartilage raw materials and makes them suitable magnitude anything regardless of [ it is good, for example, ] the mammals, fishes, or birds, it is acquired in the sequence of a cartilage raw material → digestive (proteolytic

enzyme) → impurity clearance → deodorization → filtration → spray dry desiccation (dextrin adsorption) → product (cartilage extract).

[0016] As a chondroitin salt, chondroitin sulfate, fusibility manganese salt (manganese ascorbic acid), a chondroitin ascorbic-acid salt, or a chondroitin lactate is mentioned, for example.

[0017] Although it is not limited especially by this invention although the content of the chondroitin salt of a cartilage extract changes with extraction feed, but what kind of cartilage extract may be used for it, what a high concentration article is mentioned from a viewpoint of pharmaceutical manufacturing, and is contained 15% to 95% is desirable, and what is contained 20% to 90% is more desirable.

[0018] although the pharmaceutical preparation or food of this invention changes with dosage forms, such as per day, powder, granulation, a capsule, or a tablet, as an amount of Withania sum NIFERADEYUNARU vegetable extracts — usually — as a vegetable extract — 0.05g – 2.0g (they are [ 1 ]–10g by desiccation powder conversion of natural vegetable root) extent per day — desirable — about 0.2g–0.6g — more — desirable — 0.3g–0.5 — it is good to be taken in about g.

[0019] Although the intake of the pharmaceutical preparation of this invention or the cartilage extract in food changes with contents of the chondroitin salt in a cartilage extract, its 0.05g – 10g (from 0.02g to 4g as chondroitin salt) extent per day is good, using it as the cartilage extract which contains a chondroitin salt 40%, for example, and about 0.1g–5.0g is preferably good. About 0.2g–1.0g is more preferably good.

[0020] As for the pharmaceutical preparation or food of this invention, it is desirable that a food intake is carried out so that 0.3mg – about 0.5mg per day can be taken in as WITAFERINA.

[0021] Although the pharmaceutical preparation of the Withania sum NIFERADEYUNARU plant extract and a cartilage extract or the weight ratio in the inside of food is very good in what kind of numeric value, 1:2–2:1 are desirable, for example.

[0022] Although the food of this invention is used mainly as health food (supplement), it is desirable to be used as foods for specified health use (food for special dietary uses), such as food for anti-arthritis or food for anti-rheumatism.

[0023] As the pharmaceutical preparation of this invention, or a gestalt of food, if obtained, for example with conventional methods, such as liquids and solutions, powder, a granule, a capsule, a tablet, or syrups, any will be sufficient and it will be used also as noodles, such as cone soup, sandwiches, a pan, a hamburger or spaghetti, Japanese noodles, a ramen, or a side. As a capsule, you may be any of a soft capsule or a hard filled capsule. Moreover, you may be any although the thing or glycocalyx with which it coated with that which tableted, a shellac, etc. as a tablet was carried out.

[0024] In the pharmaceutical preparation of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract can add the extract, an extract, etc. in the production process of pharmaceutical preparation, for example.

[0025] In the food of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract may add the extract, an extract, etc. in the production process of food, for example, and after they serve as food, they may add them.

[0026] 3% – 98% of the content to the inside of the pharmaceutical preparation of the Withania sum NIFERADEYUNARU plant extract used by this invention and a cartilage extract or food is desirable in pharmaceutical preparation, such as liquids and solutions, powder, a granule, a capsule, a tablet, or syrups, and is desirable with food, such as noodles, such as cone soup, sandwiches, a pan, a hamburger or spaghetti, Japanese noodles, a ramen, or a side. [ 0.03% – 20% of ]

[0027] In the pharmaceutical preparation of this invention, if it is not the object in which the efficacy effectiveness is reduced in addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added. These additives etc. can be added in the production process of the pharmaceutical preparation of this invention.

[0028] For the food of this invention, if it is not the object in which the efficacy effectiveness is reduced in addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts

obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added You may add in the production process of the food of this invention, and these additives etc. may be added after becoming food.

[0029] Chiefly, to Homo sapiens, although the pharmaceutical preparation or food of this invention is effective, it is effective in livestock or wild animals, such as pets, such as a dog or a cat, a cow, or a horse, etc., and is not limited to Homo sapiens.

[0030] As a gestalt of the feed of this invention, the thing of powder, granularity, the letter of kneading, or a pellet type is mentioned, for example. The pet food processed into the shape of a biscuit, the shape of a sausage, canning, etc. is mentioned using these feed.

[0031] Although the feed of this invention changes as an amount of Withania sum NIFERADEYUNARU vegetable extracts with forms, such as per day, powder, granularity, a letter of kneading, or a pellet type, it is usually good to be taken in by 0.01g - 20g (for them to beg [ 0.025 ]-85g by desiccation powder conversion of natural vegetable root) extent per day, and the animal as a vegetable extract.

[0032] Although the intake of the cartilage extract of the feed of this invention changes with contents of the chondroitin salt in a cartilage extract, its 0.01g - 85g (from 0.001g to 40g as chondroitin salt) extent per day is good, using it as the cartilage extract which contains a chondroitin salt 40%, for example.

[0033] As for the feed of this invention, it is desirable to make 0.025mg - about 45mg per day and an animal take in as WITAFERINA by animals made to take in, such as livestock, such as pets, such as a dog or a cat, a cow, or a horse, or a wild animal, although it is various.

[0034] Although the weight ratio in the inside of the feed of the Withania sum NIFERADEYUNARU plant extract and a cartilage extract is very good in what kind of numeric value, 1:2-2:1 are desirable, for example.

[0035] In the feed of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract can add the extract, an extract, etc. in the production process of feed, for example.

[0036] Although the content to the inside of the feed of the Withania sum NIFERADEYUNARU plant extract used by this invention and a cartilage extract varies with configurations, such as powder, granularity, a letter of kneading, or a pellet type, it is usually 0.03% - 98%.

[0037] In the feed of this invention, if it is not the object in which the efficacy effectiveness is reduced in addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added These additives etc. can be added in the production process of the feed of this invention.

[0038]

[Example(s) of Experiment] Although the example of an experiment is given to below and this invention is concretely explained to it, this invention is not limited to these.

[0039] the test approach Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract — a tablet and a shark — the tablet of only a cartilage extract (40% chondroitin sulfate content), the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, and a shark — the tablet which blended both cartilage extracts, and four kinds of tablets of a placebo which consist of crystalline celluloses and lactoses further were produced. It colored so that the coloring agent of a tea system might be added based on a crystalline cellulose and a lactose and distinction on appearance might not be made, and the tablet was used as the 300mg [/grain ] tablet. the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract end in each tablet, and a shark — the content of a cartilage extract is shown in a table 1.

[0040]

table [ ] 1 the Withania sum NIFERADEYUNARU vegetable extract end in each tablet a shark — content of a cartilage extract The end content of a vegetable extract a shark — cartilage extract content (mg/grain) (mg/grain)

end lock of vegetable extract: — formula A 90.0 0.0 sharks — cartilage extract lock: — formula B 0.0 end of 90.0 vegetable extract + — a shark — cartilage extract lock: — formula C 90.0 90.0 placebos 0.0 0.0 [0041] It

carried out, after following the pneuma of Declaration of Helsinki, fully explaining the object of an exam, the content, and the approach to the volunteer on the occasion of the administration test trial and acquiring the experimental acceptance of participation. A volunteer has a certain subjective sign considered to be arthritis and rheumatism \*\*, and 30 adult man and woman of the 40-60 years-old cost which does not have trouble in everyday life were used. The trial was performed by the single blind crossing method. Namely, 30 volunteers were divided into every ten-person three groups (Formula A, Formula B, Formula C), and each group was medicated with the placebo lock for four weeks in three grains/day. further -- a formula A group -- the end lock of a vegetable extract, and a formula B group -- a shark -- a cartilage extract lock and a formula C group -- end of vegetable extract + -- a shark -- three grains /of cartilage extract locks were prescribed for the patient for four weeks the day, respectively. The weekly questionnaire performed assessment of a symptom improvement. The examination item investigated the existence of a subjective sign within one week about the following five items based on the typical subjective sign of the criterion of the U.S. rheumatism association's chronic rheumatism, and the osteoarthritis.

Symptom 1 The \*\*\*\* burr of a joint is sensed for a morning.

Symptom 2 Three or more joints become swollen.

Symptom 3 A hand joint, metacarpophalangeal joints, and proximal interphalangeal joints become swollen.

Symptom 4 A swelling is in the same joint on either side.

Symptom 5 The start of a walk, when starting, a joint moves and a pain is sensed first. (A knee joint, a hip joint, an ankle joint, elbow joint) Within one month of an examination period, by making into those with a symptom the case where the above-mentioned symptom is also 1 time, the result made 5% of level of significance level of significance, and performed statistics processing by the chi square test [ as opposed to a placebo for the occurrence frequency ]. A result is shown in a table 2, a table 3, and a table 4.

[0042]

Trial result table 2 The end lock administration result of a vegetable extract Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula A (man) Level of significance (%) (5% of level of significance)

A symptom 1 6 5 0.653 The nothing symptom 2 1 1 1.000 The nothing symptom 3 1 1 1.000 The nothing symptom 4 2 2 1.000 The nothing symptom 5 8 6 0.238 Nothing table 3 a shark -- cartilage extract lock administration result Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula B (man) Level of significance (%) (5% of level of significance)

A symptom 1 7 6 0.639 The nothing symptom 2 1 1 1.000 The nothing symptom 3 2 1 0.531 The nothing symptom 4 1 1 1.000 The nothing symptom 5 9 7 0.264 --less table 4 end of vegetable extract + -- a shark -- cartilage extract lock administration result Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula C (man) Level of significance (%) (5% of level of significance)

A symptom 1 8 2 0.008 It is. A symptom 2 2 1 0.531 The nothing symptom 3 1 1 1.000 --less symptom 4 1 0 0.305 Nothing symptom 5 8 3 0.025 \*\*\*\* [0043] clear from a table 2, a table 3, and a table 4 -- as -- the independent administration in the vegetable extract end of a table 2, and the shark of a table 3 -- in independent administration of a cartilage extract, although the placebo and the significant difference were not about the symptom and there was little effectiveness the end of a vegetable extract, and a shark -- if a cartilage extract is simultaneously prescribed for the patient -- the symptom 1 (the \*\*\*\* burr of a joint is sensed for a morning.) of a table 4 And the symptom 5 (the start of a walk, when starting, a joint moves and a pain is sensed first.) of a table 4 The significant improvement effect was seen. this -- the end of a vegetable extract, and a shark -- the thing of the symptom of chronic rheumatism or the osteoarthritis especially a pain, or a joint which simultaneous intake stiffens, a cartilage extract is received and multiplication-effectiveness is was shown.

[0044]

[Example] Although an example is given to below and this invention is concretely explained to it, this invention is not limited to these.

[0045] 100g of the end of an example 1 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract, and a shark -- after kneading 100g (40% chondroitin sulfate) of cartilage extracts, and 20g of garlic desiccation powder to 200g of oleum rapae, one grain of inner capacity obtained the soft capsule of the gelatin coat which is 0.5g with the conventional method.

[0046] After adding 50g in 600g, 600g (20% chondroitin sulfate) of cow cartilage extracts, 800g of crystalline cellulose powder, and the end of egg shell powder in the end of an example 2 Withania sum NIFERADEYUNARU



(Withaia Somnifera Dunal) vegetable root extract and mixing, it kneaded by 75% ethanol water 1L. Furthermore, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. This desiccation granulation was packaged separately for everyg, and the stick-like granule was obtained.

[0047] After adding 100g in 600g, 600g (40% chondroitin sulfate) of cow cartilage extracts, 100g of garlic desiccation powder, 600g of crystalline cellulose powder, 300g of lactose powder, and the end of egg shell powder in the end of an example 3 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract and mixing, it kneaded by 80% ethanol water 1.4L. Furthermore, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. After adding 50g to this desiccation granulation in the end of egg shell powder, the 0.3g [ per grain ] tablet was obtained with the conventional method.

[0048] 3kg of the end of an example 4 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract, and a shark — after adding 0.4kg in 3kg (40% chondroitin sulfate) of cartilage extracts, 3.3kg of crystalline cellulose powder, and the end of egg shell powder and mixing, it kneaded by 75% ethanol water 2L. Next, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. After adding 0.2kg to this desiccation granulation in the end of egg shell powder, it tableted with the conventional method. Furthermore, it coated with the shellac and the 0.3g [ per grain ] film coated tablet agent was obtained.

[0049]

[Effect of the Invention] This invention is taking in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, and is more useful than independent intake as anti-arthritis or the pharmaceutical preparation for anti-rheumatism, food, or feed so that clearly also from the example of an experiment, and an example. Moreover, the side effect by intake was not seen, either.

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TECHNICAL FIELD

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[Field of the Invention] This invention relates to the pharmaceutical preparation which improves arthritis or rheumatism, food, for example, health food, or feed.

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[Translation done.]

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PRIOR ART

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[Description of the Prior Art] It was thought that arthritis and rheumatism had a certain cause and were conventionally generated to the bone, and intake of the calcium food for making a bone strong or calcium consolidation auxiliary food was confirmed. Moreover, in order to raise bone density, the health food which strengthened calcium to soybean isoflavone is developed. Furthermore, what combined the glucosamine salt which is the configuration monosaccharide of chitosan as palliative of arthritis, and the cartilage extract is known. The nourishment sthenia of the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, strong energy, anti-stress, and an anti-rheumatism operation have recently been checked. The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetation is vegetation of Solanaceae which grow wild in India, Nepal, or the Middle East, it is called a winter cherry (Winter Cherry) by the English name, and is called ASHUWAGANDA (Ashwagandha) in India, and also has the another name of the India ginseng radix. In India, from ancient times, more, the root and the leaf were made into medical use, put vegetable desiccation powder into tea, milk, yogurt, etc., and have been used as nourishment strong food. The Withania sum NIFERADEYUNARU (WithaiaSomnifera Dunal) vegetable extract end of a high content has come to be obtained with development of an extract technique. Moreover, the cartilage extract of a cow and a shark is used as an arthritis remedy by the chondroitin sulfate being included.

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EFFECT OF THE INVENTION

[Effect of the Invention] This invention is taking in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, and is more useful than independent intake as anti-arthritis or the pharmaceutical preparation for anti-rheumatism, food, or feed so that clearly also from the example of an experiment, and an example. Moreover, the side effect by intake was not seen, either.

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TECHNICAL PROBLEM

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[Problem(s) to be Solved by the Invention] However, it is difficult to ease arthritis and rheumatism only by a calcium consolidation or bone density lifting. Moreover, about a glucosamine salt and a cartilage extract, even if arthritis is eased in combination, there is no effectiveness in the rheumatism accompanied by the pain of a nervous system not much. Moreover, there were problems — effectiveness sufficient in just an anti-rheumatism operation of the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract is not acquired. [0004] Thus, the pharmaceutical preparation, food, and feed which can treat simultaneously the arthritis which comes from the cartilage injury of a joint etc., and the rheumatism accompanied by the pain of a nervous system, and can expect effectiveness were desired.

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MEANS

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[Means for Solving the Problem] Then, this invention persons found out that it was [ effectiveness ] more larger to have performed anti-arthritis or an anti-rheumatism operation simultaneously, and to take in simultaneously rather than independent intake by taking in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, as a result of examining many things. Consequently, the anti-arthritis which can take in simultaneously the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract or anti-rheumatism pharmaceutical preparation, food, or feed was obtained. This invention is completed based on the above-mentioned knowledge.

[0006] This invention Namely, (I) The anti-arthritis agent or anti-rheumatism agent characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, (II) An anti-arthritis agent or an anti-rheumatism agent given in (I) whose Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is an extract, (III) The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is what is obtained originally. An anti-arthritis agent or an anti-rheumatism agent given in (I) condensed 5 times to 15 times of a natural vegetable root, or (II), (IV) In the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, WITAFERIN (Withaferin) An anti-arthritis agent given in any 1 term of (I) containing site INDO sides (sitoindoside) or WITANORAIDO (Withanolide) - (III) or an anti-rheumatism agent, (V) An anti-arthritis agent or an anti-rheumatism agent given in any 1 term of (I) to which a cartilage extract is obtained from the mammals, fishes, or birds, and contains a chondroitin salt in a cartilage extract - (IV), (VI) An anti-arthritis agent or an anti-rheumatism agent given in any 1 term of (I) - (V) whose gestalt of pharmaceutical preparation is liquids and solutions, powder, a granule, a capsule, or a tablet, (VII) Food characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract, (VIII) the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract -- an extract -- it is (VII) -- the food of a publication -- (IX) The Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract is obtained originally, and it is condensed by 10 or more times of a natural vegetable root (VIII). (VII) a publication Food, (X) In the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract, WITAFERIN (Withaferin) Food given in any 1 term of (VII)- (IX) containing site INDO sides (sitoindoside) or WITANORAIDO (Withanolide), (XI) A cartilage extract is what is obtained from the mammals, fishes, or birds. Food given in any 1 term of (VII)- (X) which contains a chondroitin salt in a cartilage extract, (XII) It is related with the feed characterized by containing the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) plant extract and a cartilage extract.

[0007]

[Embodiment of the Invention] As long as the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetation in this invention contains for example, WITAFERIN (Withaferin), site INDO sides (sitoindoside), and a WITANORAIDO (Withanolide) component, what grew artificially what acted naturally as the ground student is sufficient as it. Moreover, although this vegetation may contain one component or two or more components for the above-mentioned component, its thing containing two or more components is desirable. Furthermore, this vegetation may contain WITARAIDO as a component.

[0008] For example, WITAFERIN A (WithaferinA) is contained in WITAFERIN. For example, the site INDO side VII, the site INDO side VIII, the site INDO side IX, and the site INDO side X are included in site INDO sides. For example, WITANORAIDO D and WITANORAIDO E are contained in WITANORAIDO.

[0009] It is more desirable to use an extract, although what the Withania sum NIFERADEYUNARU plant extract dried the extract which extracted the active principle with the solvent etc. and was obtained, for example from a root, a stem, a leaf, a flower, or fruits of the vegetation etc. or the root of the vegetation, a stem, a leaf, a flower,

or fruits, and was used as powder may be used. The extract contains the about 10 times as many active principle as this compared with what was used as desiccation powder.

[0010] Although the extract of the Withania sum NIFERADEYUNARU vegetable extract may use what was extracted from which thing of the root of for example, the Withania sum NIFERADEYUNARU vegetation, a stem, a leaf, a flower, or fruits, there are many contents of WITAFERINA, WITANORAIDO D, WITANORAIDOE, the site INDO side VII, the site INDO side VIII, the site INDO side IX, or the site INDO side X, and it is desirable to use the part of the root which can extract the stable amount.

[0011] Although the Withania sum NIFERADEYUNARU plant extract can usually be used anything if it is obtained originally, as for the extract, it is desirable to use the thing containing the active principle more preferably condensed 10 times to 12 times 7 times to 15 times 5 times to 15 times in the natural vegetable root.

[0012] Few objects can also be used for it although many things of the quantitative formula in the Withania sum NIFERADEYUNARU vegetable extract are desirable. For example, that in which WITAFERIN A is contained just over or below 2.00% as WITANORAIDO just over or below 0.15% can be used for the content.

[0013] The extract of the component from the Withania sum NIFERADEYUNARU vegetation can be performed using organic solvents, such as water, hot water, ethyl alcohol, or an acetone. Moreover, the mixed solvent or water solvent which combined them is sufficient, and even if those mixed rates are arbitrary, they are not cared about, and they are not limited to especially this approach.

[0014] As long as the cartilage extract in this invention is an animal which has cartilages, such as birds, such as fishes, such as the mammals, such as a cow, a goat, a whale, a sheep, or a pig, a shark, a ray, or a tuna, an ostrich, or a hen, it may be obtained from what kind of animal. Moreover, as long as it contains a chondroitin salt in a cartilage extract, what kind of animal is sufficient.

[0015] If the manufacturing method of a cartilage extract is an approach generally learned, after it collects cartilage raw materials and makes them suitable magnitude anything regardless of [ it is good, for example, ] the mammals, fishes, or birds, it is acquired in the sequence of a cartilage raw material → digestive (proteolytic enzyme) → impurity clearance → deodorization → filtration → spray dry desiccation (dextrin adsorption) → product (cartilage extract).

[0016] As a chondroitin salt, chondroitin sulfate, fusibility manganese salt (manganese ascorbic acid), a chondroitin ascorbic-acid salt, or a chondroitin lactate is mentioned, for example.

[0017] Although it is not limited especially by this invention although the content of the chondroitin salt of a cartilage extract changes with extraction feed, but what kind of cartilage extract may be used for it, what a high concentration article is mentioned from a viewpoint of pharmaceutical manufacturing, and is contained 15% to 95% is desirable, and what is contained 20% to 90% is more desirable.

[0018] although the pharmaceutical preparation or food of this invention changes with dosage forms, such as per day, powder, granulation, a capsule, or a tablet, as an amount of Withania sum NIFERADEYUNARU vegetable extracts — usually — as a vegetable extract — 0.05g – 2.0g (they are [ 1 ]–10g by desiccation powder conversion of natural vegetable root) extent per day — desirable — about 0.2g–0.6g — more — desirable — 0.3g–0.5 — it is good to be taken in about g.

[0019] Although the intake of the pharmaceutical preparation of this invention or the cartilage extract in food changes with contents of the chondroitin salt in a cartilage extract, its 0.05g – 10g (from 0.02g to 4g as chondroitin salt) extent per day is good, using it as the cartilage extract which contains a chondroitin salt 40%, for example, and about 0.1g–5.0g is preferably good. About 0.2g–1.0g is more preferably good.

[0020] As for the pharmaceutical preparation or food of this invention, it is desirable that a food intake is carried out so that 0.3mg – about 0.5mg per day can be taken in as WITAFERINA.

[0021] Although the pharmaceutical preparation of the Withania sum NIFERADEYUNARU plant extract and a cartilage extract or the weight ratio in the inside of food is very good in what kind of numeric value, 1:2–2:1 are desirable, for example.

[0022] Although the food of this invention is used mainly as health food (supplement), it is desirable to be used as foods for specified health use (food for special dietary uses), such as food for anti-arthritis or food for anti-rheumatism.

[0023] As the pharmaceutical preparation of this invention, or a gestalt of food, if obtained, for example with conventional methods, such as liquids and solutions, powder, a granule, a capsule, a tablet, or syrups, any will be sufficient and it will be used also as noodles, such as cone soup, sandwiches, a pan, a hamburger or spaghetti, Japanese noodles, a ramen, or a side. As a capsule, you may be any of a soft capsule or a hard filled capsule. Moreover, you may be any although the thing or glycocalyx with which it coated with that which tableted, a

shellac, etc. as a tablet was carried out.

[0024] In the pharmaceutical preparation of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract can add the extract, an extract, etc. in the production process of pharmaceutical preparation, for example.

[0025] In the food of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract may add the extract, an extract, etc. in the production process of food, for example, and after they serve as food, they may add them.

[0026] 3% - 98% of the content to the inside of the pharmaceutical preparation of the Withania sum NIFERADEYUNARU plant extract used by this invention and a cartilage extract or food is desirable in pharmaceutical preparation, such as liquids and solutions, powder, a granule, a capsule, a tablet, or syrups, and is desirable with food, such as noodles, such as cone soup, sandwiches, a pan, a hamburger or spaghetti, Japanese noodles, a rahmen, or a side. [ 0.03% - 20% of ]

[0027] In the pharmaceutical preparation of this invention, if it is not the object in which the efficacy effectiveness is reduced in addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added These additives etc. can be added in the production process of the pharmaceutical preparation of this invention.

[0028] For the food of this invention, if it is not the object in which the efficacy effectiveness is reduced in addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added You may add in the production process of the food of this invention, and these additives etc. may be added after becoming food.

[0029] Chiefly, to Homo sapiens, although the pharmaceutical preparation or food of this invention is effective, it is effective in livestock or wild animals, such as pets, such as a dog or a cat, a cow, or a horse, etc., and is not limited to Homo sapiens.

[0030] As a gestalt of the feed of this invention, the thing of powder, granularity, the letter of kneading, or a pellet type is mentioned, for example. The pet food processed into the shape of a biscuit, the shape of a sausage, canning, etc. is mentioned using these feed.

[0031] Although the feed of this invention changes as an amount of Withania sum NIFERADEYUNARU vegetable extracts with forms, such as per day, powder, granularity, a letter of kneading, or a pellet type, it is usually good to be taken in by 0.01g - 20g (for them to beg [ 0.025 ]-85g by desiccation powder conversion of natural vegetable root) extent per day, and the animal as a vegetable extract.

[0032] Although the intake of the cartilage extract of the feed of this invention changes with contents of the chondroitin salt in a cartilage extract, its 0.01g - 85g (from 0.001g to 40g as chondroitin salt) extent per day is good, using it as the cartilage extract which contains a chondroitin salt 40%, for example.

[0033] As for the feed of this invention, it is desirable to make 0.025mg - about 45mg per day and an animal take in as WITAFERINA by animals made to take in, such as livestock, such as pets, such as a dog or a cat, a cow, or a horse, or a wild animal, although it is various.

[0034] Although the weight ratio in the inside of the feed of the Withania sum NIFERADEYUNARU plant extract and a cartilage extract is very good in what kind of numeric value, 1:2-2:1 are desirable, for example.

[0035] In the feed of this invention, the Withania sum NIFERADEYUNARU plant extract and a cartilage extract can add the extract, an extract, etc. in the production process of feed, for example.

[0036] Although the content to the inside of the feed of the Withania sum NIFERADEYUNARU plant extract used by this invention and a cartilage extract varies with configurations, such as powder, granularity, a letter of kneading, or a pellet type, it is usually 0.03% - 98%.

[0037] In the feed of this invention, if it is not the object in which the efficacy effectiveness is reduced in



addition to the Withania sum NIFERADEYUNARU plant extract and a cartilage extract, the need is accepted, it can blend and any objects can be added. For example, oils, such as vitamins, such as lubricant, such as extracts obtained from the dietary fiber obtained from seaweed, such as fruits, such as vegetables, such as allocated type agents, such as a cellulose or a lactose, a burdock, or a garlic, an apple, or an acerola, agar, or a Fucus vesiculosus, greenstuff, legumes, fruits, bulbs, or seaweed by extract, egg shell calcium, or magnesium stearate, a vitamin A group, vitamin B group, vitamin C, or a vitamin K, a coloring agent, or oleum rapae, can be added These additives etc. can be added in the production process of the feed of this invention.

[0038]

[Example(s) of Experiment] Although the example of an experiment is given to below and this invention is concretely explained to it, this invention is not limited to these.

[0039] the test approach Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract — a tablet and a shark — the tablet of only a cartilage extract (40% chondroitin sulfate content), the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract, and a shark — the tablet which blended both cartilage extracts, and four kinds of tablets of a placebo which consist of crystalline celluloses and lactoses further were produced. It colored so that the coloring agent of a tea system might be added based on a crystalline cellulose and a lactose and distinction on appearance might not be made, and the tablet was used as the 300mg [/grain ] tablet. the Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable extract end in each tablet, and a shark — the content of a cartilage extract is shown in a table 1.

[0040]

table [ ] 1 the Withania sum NIFERADEYUNARU vegetable extract end in each tablet a shark — content of a cartilage extract The end content of a vegetable extract a shark — cartilage extract content (mg/grain)

(mg/grain)  
end lock of vegetable extract: — formula A 90.0 0.0 sharks — cartilage extract lock: — formula B 0.0 end of 90.0 vegetable extract + — a shark — cartilage extract lock: — formula C 90.0 90.0 placebos 0.0 0.0 [0041] It carried out, after following the pneuma of Declaration of Helsinki, fully explaining the object of an exam, the content, and the approach to the volunteer on the occasion of the administration test trial and acquiring the experimental acceptance of participation. A volunteer has a certain subjective sign considered to be arthritis and rheumatism \*\*, and 30 adult man and woman of the 40–60 years–old cost which does not have trouble in everyday life were used. The trial was performed by the single blind crossing method. Namely, 30 volunteers were divided into every ten–person three groups (Formula A, Formula B, Formula C), and each group was medicated with the placebo lock for four weeks in three grains/day. further — a formula A group — the end lock of a vegetable extract, and a formula B group — a shark — a cartilage extract lock and a formula C group — end of vegetable extract + — a shark — three grains /of cartilage extract locks were prescribed for the patient for four weeks the day, respectively. The weekly questionnaire performed assessment of a symptom improvement. The examination item investigated the existence of a subjective sign within one week about the following five items based on the typical subjective sign of the criterion of the U.S. rheumatism association's chronic rheumatism, and the osteoarthritis.

Symptom 1 The \*\*\*\* burr of a joint is sensed for a morning.

Symptom 2 Three or more joints become swollen.

Symptom 3 A hand joint, metacarpophalangeal joints, and proximal interphalangeal joints become swollen.

Symptom 4 A swelling is in the same joint on either side.

Symptom 5 The start of a walk, when starting, a joint moves and a pain is sensed first. (A knee joint, a hip joint, an ankle joint, elbow joint) Within one month of an examination period, by making into those with a symptom the case where the above–mentioned symptom is also 1 time, the result made 5% of level of significance level of significance, and performed statistics processing by the chi square test [ as opposed to a placebo for the occurrence frequency ]. A result is shown in a table 2, a table 3, and a table 4.

[0042]

Trial result table 2 The end lock administration result of a vegetable extract Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula A (man) Level of significance (%) (5% of level of significance)

A symptom 1 6 5 0.653 The nothing symptom 2 1 1 1.000 The nothing symptom 3 1 1 1.000 The nothing symptom 4 2 2 1.000 The nothing symptom 5 8 6 0.238 Nothing table 3 a shark — cartilage extract lock administration result Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula B (man) Level of significance (%) (5% of level of significance)

A symptom 1 7 6 0.639 The nothing symptom 2 1 1 1.000 The nothing symptom 3 2 1 0.531 The nothing symptom 4 1 1 1.000 The nothing symptom 5 9 7 0.264 -less table 4 end of vegetable extract + — a shark — cartilage extract lock administration result Manpower which appealed against the symptom Chi square test Significant difference Placebo (man) Formula C (man) Level of significance (%) (5% of level of significance) A symptom 1 8 2 0.008 It is. A symptom 2 2 1 0.531 The nothing symptom 3 1 1 1.000 -less symptom 4 1 0 0.305 Nothing symptom 5 8 3 0.025 \*\*\*\* [0043] clear from a table 2, a table 3, and a table 4 — as — the independent administration in the vegetable extract end of a table 2, and the shark of a table 3 — in independent administration of a cartilage extract, although the placebo and the significant difference were not about the symptom and there was little effectiveness the end of a vegetable extract, and a shark — if a cartilage extract is simultaneously prescribed for the patient — the symptom 1 (the \*\*\*\* burr of a joint is sensed for a morning.) of a table 4 And the symptom 5 (the start of a walk, when starting, a joint moves and a pain is sensed first.) of a table 4 The significant improvement effect was seen. this — the end of a vegetable extract, and a shark — the thing of the symptom of chronic rheumatism or the osteoarthritis especially a pain, or a joint which simultaneous intake stiffens, a cartilage extract is received and multiplication-effectiveness is was shown.

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EXAMPLE

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[Example] Although an example is given to below and this invention is concretely explained to it, this invention is not limited to these.

[0045] 100g of the end of an example 1 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract, and a shark — after kneading 100g (40% chondroitin sulfate) of cartilage extracts, and 20g of garlic desiccation powder to 200g of oleum rapae, one grain of inner capacity obtained the soft capsule of the gelatin coat which is 0.5g with the conventional method.

[0046] After adding 50g in 600g, 600g (20% chondroitin sulfate) of cow cartilage extracts, 800g of crystalline cellulose powder, and the end of egg shell powder in the end of an example 2 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract and mixing, it kneaded by 75% ethanol water 1L. Furthermore, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. This desiccation granulation was packaged separately for everyg, and the stick-like granule was obtained.

[0047] After adding 100g in 600g, 600g (40% chondroitin sulfate) of cow cartilage extracts, 100g of garlic desiccation powder, 600g of crystalline cellulose powder, 300g of lactose powder, and the end of egg shell powder in the end of an example 3 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract and mixing, it kneaded by 80% ethanol water 1.4L. Furthermore, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. After adding 50g to this desiccation granulation in the end of egg shell powder, the 0.3g [ per grain ] tablet was obtained with the conventional method.

[0048] 3kg of the end of an example 4 Withania sum NIFERADEYUNARU (Withaia Somnifera Dunal) vegetable root extract, and a shark — after adding 0.4kg in 3kg (40% chondroitin sulfate) of cartilage extracts, 3.3kg of crystalline cellulose powder, and the end of egg shell powder and mixing, it kneaded by 75% ethanol water 2L. Next, the wet particle size regulation was carried out with the speed mill, and it dried at 60 degrees C. After adding 0.2kg to this desiccation granulation in the end of egg shell powder, it tableted with the conventional method. Furthermore, it coated with the shellac and the 0.3g [ per grain ] film coated tablet agent was obtained.

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最終頁に続く

(54) 【発明の名称】 抗関節炎もしくは抗リュウマチ製剤、食品又は飼料

(57) 【要約】

【課題】 カルシウム摂取での関節炎やリュウマチの緩和は困難であり、グルコサミン塩と軟骨抽出物とを組み合わせで関節炎を緩和されても神経系の痛みを伴うリュウマチにはあまり効果がない。又、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキスの抗リュウマチ作用だけでは十分な効果が得られないなどの問題がある。

【解決手段】 ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする抗関節炎剤又は抗リュウマチ剤を提供する。

## 【特許請求の範囲】

【請求項 1】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする抗関節炎剤又は抗リュウマチ剤

【請求項 2】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物がエキスである請求項 1 に記載の抗関節炎剤又は抗リュウマチ剤

【請求項 3】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物が根から得られるものであって、天然の植物根の 5 倍～15 倍に濃縮されたものである請求項 1 又は 2 に記載の抗関節炎剤又は抗リュウマチ剤

【請求項 4】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキス中にウィタフェリン類 (Withaferin)、サイトインドサイド類 (sitoindoside) 又はウィタノライド類 (Withanolide) を含有する請求項 1～3 のいずれか 1 項に記載の抗関節炎剤又は抗リュウマチ剤

【請求項 5】軟骨抽出物が哺乳類、魚類又は鳥類から得られるものであって、軟骨抽出物中にコンドロイチン塩を含有する請求項 1～4 のいずれか 1 項に記載の抗関節炎剤又は抗リュウマチ剤

【請求項 6】製剤の形態が液剤、散剤、顆粒剤、カプセル剤もしくは錠剤である請求項 1～5 のいずれか 1 項に記載の抗関節炎剤又は抗リュウマチ剤

【請求項 7】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする食品

【請求項 8】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物がエキスである請求項 7 に記載の食品

【請求項 9】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物が根から得られるものであって、天然の植物根の 10 倍以上に濃縮されたものである請求項 7 又は 8 に記載の食品

【請求項 10】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物中にウィタフェリン類 (Withaferin)、サイトインドサイド類 (sitoindoside) 又はウィタノライド類 (Withanolide) を含有する請求項 7～9 のいずれか 1 項に記載の食品

【請求項 11】軟骨抽出物が哺乳類、魚類又は鳥類から得られるものであって、軟骨抽出物中にコンドロイチン塩を含有する請求項 7～10 のいずれか 1 項に記載の食品

【請求項 12】ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする飼料

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】本発明は、関節炎もしくはリ

ュウマチを改善する製剤、食品、例えば健康食品、又は飼料に関するものである。

## 【0002】

【従来の技術】従来、関節炎やリュウマチは骨に何らかの原因があって発生していると考えられ、骨を丈夫にするためのカルシウム食品やカルシウム強化補助食品の摂取が有効とされていた。又、骨密度を上げるために大豆イソフラボンにカルシウムを強化した健康食品が開発されている。更に、関節炎の緩和剤としてキトサンの構成単糖であるグルコサミン塩と軟骨抽出物とを組み合わせたものが知られている。最近になってウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキスの滋養強壮、強精、抗ストレス、抗リュウマチ作用が確認されてきた。ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物は、インド、ネパールや中東に自生するナス科の植物で、英名でウインターチェリー (Winter Cherry) と呼ばれ、又、インドではアシュワガンダ (Ashwagandha) と呼ばれ、インド人参の異名もある。インドでは古来より根、葉が薬用にされ、植物の乾燥粉末を茶やミルク、ヨーグルトなどに入れ、滋養強壮食品として用いられてきた。抽出技術の発達に伴い高含量のウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキス末が得られるようになってきた。また、牛、鯨の軟骨抽出物はコンドロイチン硫酸塩を含んでいる事で関節炎治療薬として使用されている。

## 【0003】

【発明が解決しようとする課題】しかし、カルシウム強化や骨密度上昇だけでは関節炎やリュウマチを緩和することが困難である。又、グルコサミン塩と軟骨抽出物とを組み合わせで関節炎を緩和されても神経系の痛みを伴うリュウマチにはあまり効果がない。又、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキスの抗リュウマチ作用だけでは十分な効果が得られないなどの問題があった。

【0004】このように、関節の軟骨損傷等からくる関節炎及び神経系の痛みを伴うリュウマチを同時に治療でき効果が期待できる製剤、食品及び飼料が望まれていた。

## 【0005】

【課題を解決するための手段】そこで本発明者らは種々検討した結果、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを同時に摂取する事で抗関節炎又は抗リュウマチ作用を同時に起こない、単独摂取よりも同時に摂取した方がより効果が大きい事を見いだした。その結果、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを同時に摂取できる抗関節炎もしくは抗リュウマチ製剤、食品又は飼料が得られた。本発明は上記知見に基づいて完成されたものである。

【0006】即ち、本発明は、(I) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする抗関節炎剤又は抗リュウマチ剤、(II) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物がエキスである(I)に記載の抗関節炎剤又は抗リュウマチ剤、(III) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物が根から得られるものであって、天然の植物根の5倍〜15倍に濃縮されたものである(I)又は(II)に記載の抗関節炎剤又は抗リュウマチ剤、(IV) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキス中にウィタフェリン類 (Withaferin)、サイトインドサイド類 (sitoindoside) 又はウィタノライド類 (Withanolide) を含有する(I)〜(III)のいずれか1項に記載の抗関節炎剤又は抗リュウマチ剤、(V) 軟骨抽出物が哺乳類、魚類又は鳥類から得られるものであって、軟骨抽出物中にコンドロイチン塩を含有する(I)〜(IV)のいずれか1項に記載の抗関節炎剤又は抗リュウマチ剤、(VI) 製剤の形態が液剤、散剤、顆粒剤、カプセル剤もしくは錠剤である(I)〜(V)のいずれか1項に記載の抗関節炎剤又は抗リュウマチ剤、(VII) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする食品、(VIII) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物がエキスである(VII)に記載の食品、(IX) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物が根から得られるものであって、天然の植物根の10倍以上に濃縮されたものである(VII)又は(VIII)に記載の食品、(X) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物中にウィタフェリン類 (Withaferin)、サイトインドサイド類 (sitoindoside) 又はウィタノライド類 (Withanolide) を含有する(VII)〜(IX)のいずれか1項に記載の食品、(XI) 軟骨抽出物が哺乳類、魚類又は鳥類から得られるものであって、軟骨抽出物中にコンドロイチン塩を含有する(VII)〜(X)のいずれか1項に記載の食品、(XII) ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを含有することを特徴とする飼料、に関する。

【0007】

【発明の実施の形態】本発明におけるウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物は、例えばウィタフェリン類 (Withaferin)、サイトインドサイド類 (sitoindoside)、ウィタノライド類 (Withanolide) 成分を含有するものであれば、天然に地生したものでも人工的に栽培したものでもよい。また、この植物は、上記の成分を1成分又は複数の成分を含んでいて

も良いが、複数の成分を含んでいるものが好ましい。更に、この植物は、ウィタライド類を成分として含んでいるものであっても良い。

【0008】ウィタフェリン類には、例えばウィタフェリンA (WithaferinA) が含まれている。サイトインドサイド類には、例えばサイトインドサイドVII、サイトインドサイドVIII、サイトインドサイドIX、サイトインドサイドXが含まれている。ウィタノライド類には、例えばウィタノライドD、ウィタノライドEが含まれている。

【0009】ウィザニアサムニフェラデュナル植物抽出物は、例えばその植物の根、茎、葉、花又は果実等から有効成分を溶媒等で抽出して得られたエキス又はその植物の根、茎、葉、花又は果実等を乾燥して粉末としたものを用いても良いが、エキスをういた方が好ましい。エキスは、乾燥粉末としたものに比べて約10倍の有効成分を含有している。

【0010】ウィザニアサムニフェラデュナル植物エキスの抽出は、例えばウィザニアサムニフェラデュナル植物の根、茎、葉、花又は果実のいずれのものから抽出したものをういても良いが、ウィタフェリンA、ウィタノライドD、ウィタノライドE、サイトインドサイドVII、サイトインドサイドVIII、サイトインドサイドIX又はサイトインドサイドXの含有量が多く、安定した量を抽出可能な根の部分を用いるのが好ましい。

【0011】ウィザニアサムニフェラデュナル植物抽出物は、通常、根から得られるものであれば何でもよいことができるが、その抽出物は、天然の植物根を5倍〜15倍、好ましくは7倍〜15倍、より好ましくは10倍〜12倍に濃縮された有効成分を含むものを用いるのが好ましい。

【0012】ウィザニアサムニフェラデュナル植物エキス中の成分含有量は、多いものが望ましいが、少ない物でも使用することができる。例えばその含有量は、ウィタフェリンAが0.15%前後、ウィタノライド類として2.00%前後含まれているものを用いることができる。

【0013】ウィザニアサムニフェラデュナル植物からの成分の抽出は、例えば水、熱水又はエチルアルコールもしくはアセトン等の有機溶媒を用いて行なうことができる。また、それらを組み合わせた混合溶媒又は含水溶媒でもよく、それらの混合割合は任意であっても構わないし、特にこの方法に限定されるものではない。

【0014】本発明における軟骨抽出物は、例えば牛、山羊、鯨、羊もしくは豚等の哺乳類、鮫、エイもしくはマグロ等の魚類又はダチョウもしくは鶏等の鳥類等の軟骨を有する動物であれば如何なる動物から得られるものであってもよい。また、軟骨抽出物中にコンドロイチン塩を含有するものであれば如何なる動物でもよい。

【0015】軟骨抽出物の製造法は、一般的に知られて

いる方法なら何でも良く、例えば哺乳類、魚類又は鳥類に関係なく、軟骨原料を収集して適当な大きさにしてから、軟骨原料→消化（蛋白分解酵素）→夾雑物除去→脱臭→濾過→スプレードライ乾燥（デキストリン吸着）→製品（軟骨抽出物）という順序で得られる。

【0016】コンドロイチン塩としては、例えばコンドロイチン硫酸、可溶性マンガン塩（マンガン・アスコルビン酸）、コンドロイチンアスコルビン酸塩又はコンドロイチン乳酸塩が挙げられる。

【0017】軟骨抽出物のコンドロイチン塩の含有量は、抽出原料によって異なるが、本発明では、特に限定されず、如何なる軟骨抽出物を用いても良いが、製剤加工の観点から高濃度品が挙げられ、15%～95%含有されるものが好ましく、20%～90%含有されているものがより好ましい。

【0018】本発明の製剤又は食品は、ウィザニアサムニフェラデュナル植物エキス量として1日あたり、粉末、顆粒、カプセル又は錠剤などの剤形によって異なるが、通常、植物エキスとして1日当たり0.05g～2.0g（天然植物根の乾燥粉末換算で1g～10g）程度、好ましくは0.2g～0.6g程度、より好ましくは0.3g～0.5g程度摂取されるのがよい。

【0019】本発明の製剤又は食品中の軟骨抽出物の摂取量は、軟骨抽出物中のコンドロイチン塩の含量によって異なるが、例えばコンドロイチン塩を40%含有する軟骨抽出物として1日当たり0.05g～1.0g（コンドロイチン塩として0.02gから4g）程度がよく、好ましくは0.1g～5.0g程度がよい。より好ましくは0.2g～1.0g程度がよい。

【0020】本発明の製剤又は食品は、ウィタフェリンAとして1日当たり0.3mg～0.5mg程度摂取できるように、摂取されるのが好ましい。

【0021】ウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物の製剤又は食品中での重量比は、いかなる数値をとっても良いが、例えば1:2～2:1が好ましい。

【0022】本発明の食品は、主として健康食品（栄養補助食品）として用いられるが、抗関節炎用食品又は抗リュウマチ用食品等の特定保健用食品（特別用途食品）として用いられることが好ましい。

【0023】本発明の製剤又は食品の形態としては、例えば液剤、散剤、顆粒剤、カプセル剤、錠剤又はシロップ剤など常法で得られるものであれば何れでも良いし、また、コーンスープ、サンドイッチ、パン、ハンバーグ又はスバゲティー、うどん、ラーメンもしくはそば等の麺類としても用いられる。カプセル剤としては、軟カプセル又は硬カプセルのいずれであっても良い。また、錠剤としては、打錠したもの、セラック等でコーティングしたもの又は糖衣をしたもののいずれであっても良い。

【0024】本発明の製剤において、ウィザニアサムニ

フェラデュナル植物抽出物と軟骨抽出物は、例えばそのエキス、抽出物等を製剤の製造工程中に添加することができる。

【0025】本発明の食品において、ウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物は、例えばそのエキス、抽出物等を食品の製造工程中に添加しても良いし、食品となってから添加しても良い。

【0026】本発明で使用するウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物の製剤又は食品中への含量は、例えば液剤、散剤、顆粒剤、カプセル剤、錠剤又はシロップ剤等の製剤では3%～98%が好ましく、コーンスープ、サンドイッチ、パン、ハンバーグ又はスバゲティー、うどん、ラーメンもしくはそば等の麺類等の食品では0.03%～20%が好ましい。

【0027】本発明の製剤には、ウィザニアサムニフェラデュナル植物抽出物、軟骨抽出物以外に効能効果を低下させる物でなければ如何なる物でも必要に応じて配合、添加することができる。例えば、セルロースもしくは乳糖等の賦型剤、ゴボウもしくはニンニク等の野菜、リンゴもしくはアセロラ等の果実類又は天草もしくはコンブ等の海草類から得られる食物繊維、野菜類、豆類、果実類、宿根草類もしくは海草類等から抽出によって得られたエキス類、卵殻カルシウムもしくはステアリン酸マグネシウム等の滑沢剤、ビタミンA群、ビタミンB群、ビタミンCもしくはビタミンK等のビタミン類、着色料又は菜種油等の油を加えることができる。これらの添加物等は、例えば本発明の製剤の製造工程中に添加することができる。

【0028】本発明の食品には、ウィザニアサムニフェラデュナル植物抽出物、軟骨抽出物以外に効能効果を低下させる物でなければ如何なる物でも必要に応じて配合、添加することができる。例えば、セルロースもしくは乳糖等の賦型剤、ゴボウもしくはニンニク等の野菜、リンゴもしくはアセロラ等の果実類又は天草もしくはコンブ等の海草類から得られる食物繊維、野菜類、豆類、果実類、宿根草類もしくは海草類等から抽出によって得られたエキス類、卵殻カルシウムもしくはステアリン酸マグネシウム等の滑沢剤、ビタミンA群、ビタミンB群、ビタミンCもしくはビタミンK等のビタミン類、着色料又は菜種油等の油を加えることができる。これらの添加物等は、例えば本発明の食品の製造工程中に添加しても良いし、食品となってから添加しても良い。

【0029】本発明の製剤又は食品は、専らヒトに対して有効であるが、犬もしくは猫等の愛玩動物、牛もしくは馬等の家畜又は野生動物等にも有効であり、ヒトに限定されるものではない。

【0030】本発明の飼料の形態としては、例えば粉末状、顆粒状、練り状又はペレット状のものが挙げられる。これらの飼料を使って、例えばビスケット状、ソーセージ状又は缶詰等に加工されたペットフードが挙げら

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れる。

【0031】本発明の飼料は、ウィザニアサムニフェラデュナル植物エキス量として1日あたり、粉末状、顆粒状、練り状又はベレット状などの形によって異なるが、通常、植物エキスとして1日当たり0.01g~20g（天然植物根の乾燥粉末換算で0.025g~85g）程度、動物に摂取されるのがよい。

【0032】本発明の飼料の軟骨抽出物の摂取量は、軟骨抽出物中のコンドロイチン塩の含量によって異なるが、例えばコンドロイチン塩を40%含有する軟骨抽出物として1日当たり0.01g~85g（コンドロイチン塩として0.001gから40g）程度がよい。

【0033】本発明の飼料は、犬もしくは猫等の愛玩動物、牛もしくは馬等の家畜又は野生動物等の摂取させる動物によって様々であるが、ウィタフェリンAとして1日当たり0.025mg~45mg程度、動物に摂取させるのが好ましい。

【0034】ウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物の飼料中での重量比は、いかなる数値をとっても良いが、例えば1:2~2:1が好ましい。

【0035】本発明の飼料において、ウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物は、例えばそのエキス、抽出物等を飼料の製造工程中に添加することができる。

【0036】本発明で使用するウィザニアサムニフェラデュナル植物抽出物と軟骨抽出物の飼料中への含量は、粉末状、顆粒状、練り状又はベレット状等の形状によって、様々であるが、通常、0.03%~98%である。

【0037】本発明の飼料には、ウィザニアサムニフェラデュナル植物抽出物、軟骨抽出物以外に効能効果を低

表1

各錠剤中のウィザニアサムニフェラデュナル植物エキス末と軟骨抽出物の含有量

	植物エキス末含有量 (mg/粒)	軟骨抽出物含有量 (mg/粒)
植物エキス末錠：処方A	90.0	0.0
軟骨抽出物錠：処方B	0.0	90.0
植物エキス末+軟骨抽出物錠：処方C	90.0	90.0
プラセボ	0.0	0.0

#### 【0041】投与試験

試験に際しては、ヘルシンキ宣言の精神に則り、ボランティアには本試験の目的、内容、方法について十分に説明して試験の参加の同意を得た上で実施した。ボランティアには関節炎及びリュウマチ症と思われる何らかの自覚症状があり、日常生活に支障のない40~60歳代の成人男女30名を用いた。試験はシングルブラインド・クロスオーバー法で行なった。すなわち、30名のボランティアを10名づつ3つのグループ（処方A、処方B、処方C）にわけ、各グループにプラセボ錠を3粒／

\*下させる物でなければ如何なる物でも必要に応じて配合、添加することができる。例えば、セルロースもしくは乳糖等の賦型剤、ゴボウもしくはニンニク等の野菜、リンゴもしくはアセロラ等の果実類又は天草もしくはコンブ等の海藻類から得られる食物繊維、野菜類、豆類、果実類、宿根草類もしくは海藻類等から抽出によって得られたエキス類、卵殻カルシウムもしくはステアリン酸マグネシウム等の滑沢剤、ビタミンA群、ビタミンB群、ビタミンCもしくはビタミンK等のビタミン類、着色料又は菜種油等の油を加えることができる。これらの添加物等は、例えば本発明の飼料の製造工程中に添加することができる。

#### 【0038】

【実験例】以下に実験例を挙げて本発明を具体的に説明するが、本発明はこれらに限定されるものではない。

#### 【0039】テスト方法

ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキスのみ錠剤、軟骨抽出物 (40%コンドロイチン硫酸含有) のみの錠剤、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキスと軟骨抽出物の両方を配合した錠剤、さらに結晶性セルロースと乳糖からなるプラセボの4種類の錠剤を作製した。錠剤は結晶性セルロースと乳糖をベースに茶系の着色料を添加して外見上の見分けができないように着色し、300mg/粒の錠剤とした。各錠剤中のウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物エキス末と軟骨抽出物の含有量を表1に示す。

#### 【0040】

日を4週間投与した。さらに処方Aグループには植物エキス末錠、処方Bグループには軟骨抽出物錠、処方Cグループには植物エキス末+軟骨抽出物錠をそれぞれ3粒/日、4週間投与した。症状改善の評価は、1週間毎のアンケートにより行なった。調査項目は米国リュウマチ協会の慢性リュウマチの診断基準と変形性関節症の代表的な自覚症状をもとに以下の5項目に関し1週間以内で自覚症状の有無を調査した。

症状1 朝に関節のこわばりを感じる。

症状2 関節が3箇所以上腫れる。



症状3 手関節、中手指節関節、近位指節間関節が腫れる。

症状4 左右の同じ関節に腫れがある。

症状5 歩き始めや立ち上がる時など関節の動かし始めに痛みを感じる。(膝関節、股関節、足関節、肘関節)

結果は調査期間の1ヶ月以内で上記症状が1回でもあつ\*

#### 試験結果

表2

#### 植物エキス末錠投与結果

	症状を訴えた人数		カイ2乗検定 危険率(%)	有意差 (危険率5%)
	プラセボ(人)	処方A(人)		
症状1	6	5	0.653	なし
症状2	1	1	1.000	なし
症状3	1	1	1.000	なし
症状4	2	2	1.000	なし
症状5	8	6	0.238	なし

表3

#### 鮫軟骨抽出物錠投与結果

	症状を訴えた人数		カイ2乗検定 危険率(%)	有意差 (危険率5%)
	プラセボ(人)	処方B(人)		
症状1	7	6	0.639	なし
症状2	1	1	1.000	なし
症状3	2	1	0.531	なし
症状4	1	1	1.000	なし
症状5	9	7	0.264	なし

表4

#### 植物エキス末+鮫軟骨抽出物錠投与結果

	症状を訴えた人数		カイ2乗検定 危険率(%)	有意差 (危険率5%)
	プラセボ(人)	処方C(人)		
症状1	8	2	0.008	あり
症状2	2	1	0.531	なし
症状3	1	1	1.000	なし
症状4	1	0	0.305	なし
症状5	8	3	0.025	あり

【0043】表2、表3及び表4から明らかなように、表2の植物エキス末の単独投与や表3の鮫軟骨抽出物の単独投与では症状に関してプラセボと有意差はなく、効果は少なかったが、植物エキス末と鮫軟骨抽出物を同時に投与すると、表4の症状1（朝に関節のこわばりを感じる。）及び表4の症状5（歩き始めや立ち上がる時など関節の動かし始めに痛みを感じる。）に有意な改善効果がみられた。このことは植物エキス末と鮫軟骨抽出物を同時摂取が慢性リュウマチや変形性関節症の症状、特に痛みや関節のこわばりに対し相乗的な効果があることが示された。

【0044】

【実施例】以下に実施例を挙げて本発明を具体的に説明するが、本発明はこれらに限定されるものではない。

【0045】実施例1

ウィザニアサムニフェラデュナル(Withaia Somnifera

\*た場合を症状ありとして、その発生頻度をプラセボに対するカイ2乗検定により、危険率5%を有意水準として統計処理を行なった。結果は、表2、表3及び表4に示す。

【0042】

40 ウィザニアサムニフェラデュナル(Withaia Somnifera Dunal)植物根エキス末100gと鮫軟骨抽出物(40%コンドロイチン硫酸)100gとにんにく乾燥粉末20gを菜種油200gに練合した後、常法により1粒の内容量が0.5gのゼラチン皮膜の軟カプセルを得た。

【0046】実施例2

40 ウィザニアサムニフェラデュナル(Withaia Somnifera Dunal)植物根エキス末600gと牛軟骨抽出物(20%コンドロイチン硫酸)600gと結晶性セルロース粉末800gと卵殻粉末50gを加えて混合した後、75%エタノール水1Lで練合した。更に、スピードミルで湿式整粒して60℃で乾燥した。この乾燥顆粒を1g毎に分包してステック状の顆粒剤を得た。

【0047】実施例3

40 ウィザニアサムニフェラデュナル(Withaia Somnifera Dunal)植物根エキス末600gと牛軟骨抽出物(40%コンドロイチン硫酸)600gとにんにく乾燥粉末1

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00gと結晶性セルロース粉末600gと乳糖粉末300gと卵殻粉末100gを加えて混合した後、80%エタノール水1.4Lで練合した。更に、スピードミルで湿式整粒して60℃で乾燥した。この乾燥顆粒に卵殻粉末50gを加えた後、常法により1粒あたり0.3gの錠剤を得た。

## 【0048】実施例4

ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物根エキス末3kgと鮫軟骨抽出物(40%コンドロイチン硫酸)3kgと結晶性セルロース粉末3.3kgと卵殻粉末0.4kgを加えて混合した後、75%エタノール水2Lで練合した。次に、スピードミ\*

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\*ルで湿式整粒して60℃で乾燥した。この乾燥顆粒に卵殻粉末0.2kgを加えた後、常法により打錠した。更に、セラックでコーティングして1粒あたり0.3gのフィルムコーティング錠剤を得た。

## 【0049】

【発明の効果】実験例及び実施例からも明らかなように本発明は、ウィザニアサムニフェラデュナル (Withaia Somnifera Dunal) 植物抽出物と軟骨抽出物とを同時に摂取する事で、単独摂取よりも抗関節炎もしくは抗リュウマチ用製剤、食品又は飼料として有用である。又、摂取による副作用も見られなかった。

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